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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
(JACKSON DIVISION)

TOMAS MADRO BANDARIES.

Plaintiff,

1

Pfizer Inc., Pharmacia
Corporation, and G.D. Seale, LLC.

Defendants.

Case No. 3:08-cv-00222-TSL-JCS

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

Tomas Madro Bandaries, Plaintiff, by and through counsel and pursuant to applicable law, brings this action against Defendants PFIZER INC., PHARMACIA CORPORATION, and G.D. SEARLE, LLC (hereafter collectively “Defendants”) and alleges as follows:

1 **I. PARTIES**

2 1. This is an action for damages arising from Defendants' design,
3 manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe
4 medication Valdecoxib, trade name BEXTRA® ("BEXTRA").

5 2. Plaintiff is an adult resident citizen of the State of Mississippi (Lincoln
6 County) since May 28, 2007. At the time of his Bextra ingestion and injury he was an adult
7 resident citizen of the State of Arizona.

8 3. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its
9 principal place of business in New York, New York. In 2003, Pfizer acquired Pharmacia
10 Corporation for nearly \$60 billion. At all relevant times Pfizer and/or its predecessors in interest
11 were engaged in the business of designing, testing, manufacturing, packaging, marketing,
12 distributing, promoting, and selling the drug Valdecoxib, under the trade name BEXTRA in
13 Illinois, Arizona, Mississippi, California and nationwide and in Mexico.

14 4. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co.
15 ("Searle") is a Delaware corporation with its principal place of business in Illinois. At all relevant
16 times, Searle has been engaged in the business of marketing and selling BEXTRA in Illinois,
17 Arizona, Mississippi, California and nationwide and in Mexico. Searle is a subsidiary of Pfizer,
18 acting as its agent and alter ego in all matters alleged within this Complaint.

19 5. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware
20 corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia,
21 and its predecessors in interest have been engaged in the business of designing, testing,
22 manufacturing, packaging, marketing, distributing, promoting, and selling BEXTRA Illinois,
23 Arizona, Mississippi, California and nationwide and in Mexico.

24 **II. JURISDICTION AND VENUE**

25 6. This is an action for damages, which exceeds seventy-five thousand dollars
26 (\$75,000.00).

27 7. There is complete diversity of citizenship between the Plaintiff and
28 Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A.

1 § 1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and
2 because there is complete diversity of citizenship between Plaintiff and Defendants.

3 8. Venue is proper in this United States Judicial District pursuant to
4 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in
5 this district, thereby receiving substantial financial benefit and profits from the dangerous product
6 in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

7 9. At all relevant times herein, Defendants were in the business of designing,
8 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and
9 selling their product, BEXTRA. Defendants at all times relevant hereto designed, developed,
10 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce
11 (including Mississippi) the aforementioned prescription drug. Defendants do substantial business
12 in the State of Mississippi and within this Federal Judicial District, advertise in this district,
13 receive substantial compensation and profits from sales of BEXTRA in this District, and made
14 material omissions and misrepresentations and breaches of warranties in this District so as to
15 subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged
16 herein each defendant acted as the agent for each of the other defendants, or those defendant's
17 predecessors in interest.

18 **III. FACTUAL BACKGROUND**

19 **A. Facts Regarding Plaintiff**

20 10. Tomas Madro Bandaries was prescribed, and began taking, BEXTRA
21 20mg twice per day beginning in January 2003 as prescribed by Dr. Belinda Uhall in Tucson,
22 Arizona. His initial Bextra purchases were from Walgreen's pharmacy at 6767 E. Broadway
23 Boulevard in Tucson. However, his insurance failed to cover the cost, so after December 8, 2003
24 he purchased his Bextra thirty miles away in Mexico where it was much less expensive.

25 11. Unaware of the risks presented by BEXTRA, or that BEXTRA was the
26 cause of injuries, Plaintiff continued to take BEXTRA until he stopped in early 2007 after
27

1 learning of Bextra's April 7, 2005 market withdrawal by reading about it in a medical journal at a
2 doctor's office.

3 12. Plaintiff suffered a **heart attack on** February 5, 2007 as a direct result of
4 Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations leading to
5 Plaintiff's ingestion of BEXTRA.

6 13. Plaintiff used BEXTRA in a proper and reasonably foreseeable manner and
7 used it in a condition that was substantially the same as the condition in which it was
8 manufactured and sold.

9 14. Plaintiff would not have used BEXTRA had Defendants properly disclosed
10 the risks associated with the drug.

11 **B. Facts Regarding Bextra and Bextra's Market Launch**

12 15. Bextra is one of a class of pain medications called non-steroidal anti-
13 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade
14 name Advil) are examples of well-known NSAIDs.

15 16. NSAIDs reduce pain by blocking the body's production of pain
16 transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX
17 enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and
18 COX-2 enzymes.

19 17. In addition to decreasing inflammation, the prostaglandins that are
20 supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the
21 stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the
22 medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric
23 tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including
24 stomach ulceration and bleeding.

25 18. Prostaglandin I2 is the predominant cyclooxygenase product in
26 endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation,
27 and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit
28

1 Thromboxane A2 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected.
2 Thromboxane A2 is a potent platelet aggregator and vasoconstrictor, which is synthesized by
3 platelets. Therefore, while the older NSAIDS suppress platelet aggregation and vasoconstriction,
4 the COX-2 inhibitors support it.

5 19. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore
6 pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected,
7 traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause
8 blood clots, rather they actually reduce the risk of clots and help protect heart function.

9 20. Defendants and other pharmaceutical companies set out to remedy these
10 ulcer and bleeding problems suffered by some NSAID users by developing “selective” inhibitors
11 that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of
12 gastric tissue while still reducing inflammation.

13 21. In making this decision, Defendants and their predecessors in interest either
14 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
15 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
16 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,
17 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

18 22. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor
19 drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and
20 consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In
21 May 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

22 23. Seeking increased market share in this extremely lucrative market,
23 Defendants, and their predecessors in interest, also sought approval of a “second generation”
24 selective COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for the
25 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief
26 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

1 24. The FDA granted approval of the new drug on November 16, 2001, for two
2 particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms
3 of osteoarthritis and rheumatoid arthritis.

4 25. The FDA did not grant approval to market and promote Bextra for the
5 management or prevention of acute pain.

6 26. The FDA did not grant approval to promote Bextra as more effective than
7 other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers
8 or gastric bleeding.

9 27. Even without a label that allowed Defendants to legitimately claim superior
10 safety, when Defendants, and their predecessors-in-interest, began marketing Bextra in early
11 2002, Defendants and their representatives and agents misrepresented the safety profile of Bextra
12 to consumers, including Plaintiff, the medical community, healthcare providers, and third party
13 payers. Defendants proceeded to promote, market, sell, and distribute Bextra as a much safer and
14 more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

15 C. **Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.**

16 28. The potential for cardiovascular risk of selective COX-2 inhibitors was
17 known to Defendants long before the FDA granted market approval in November 2, 2001. By
18 1997, and prior to the submission of the New Drug Application (the "NDA") for Bextra,
19 Defendants was aware that, by inhibiting COX-2, Bextra altered the homeostatic balance between
20 prostacyclin synthesis and thromboxane and thereby, increased the prothrombotic effects of the
21 drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of*
22 *Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at
23 954. Although all COX-2 inhibitors have this mechanism of action, Bextra was the most
24 selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to
25 cause adverse cardiovascular and cerebrovascular events.

26 29. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of
27 Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on
28

1 October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as
2 Bextra, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet
3 aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

4 30. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the
5 FDA for Bextra, omitting information about the extent of the risks associated with Bextra.
6 Without a complete picture of the potential hazards associated with the drug, the FDA approved
7 Bextra on or about November 16, 2001.

8 31. Based on the studies performed on Celebrex, Vioxx, Bextra, and other
9 COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely
10 conducted, Defendants knew when Bextra was being developed and tested that selective COX-2
11 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific
12 additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies
13 show that selective COX-2 inhibitors, including Bextra, decrease blood levels of a prostacyclin.
14 When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart
15 attack, and stroke.

16 32. On December 9, 2004, the FDA issued new information on side effects
17 associated with the use of Bextra and required the addition of certain warnings to, and the
18 strengthening of other warnings on, the Bextra label. The enhanced warnings followed in the
19 wake of the results of additional cardiovascular studies performed by Defendants, as well as
20 numerous complaints to the FDA regarding severe skin reactions.

21 33. Yet well prior to this warning, Defendants had knowledge of the coronary
22 and cardiovascular safety risks of Bextra from several studies. *See e.g.*, Otto, E.O., *Efficacy and*
23 *Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing*
24 *Coronary Artery Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery*, June
25 2003 at 1481.

26 34. Even Defendants' own (and Pfizer funded) post- drug approval meta-
27 analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data
28

1 showing an increased cardiovascular risk in patients treated with Bextra after undergoing
2 coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood
3 clots in the legs and lungs. The results were particularly relevant and striking as each of the study
4 participants who were a post-bypass surgery patient was taking anti-clotting agents at the time
5 their exposure to Bextra was being tracked.

6 35. In mid-January 2005, a peer-reviewed paper from the University of
7 Pennsylvania found that in patients having heart bypass surgery, those who took Bextra in the
8 intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a
9 heart attack or stroke.

10 36. From February 16-18, 2005, the FDA's Drug Safety and Risk Management
11 Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine
12 the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham
13 testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at
14 about the same rate as cigarette smoking, hypertension, and diabetes.

15 37. Despite years of studies on selective COX-2 inhibitors, as well as the
16 disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any
17 action to protect the health and welfare of patients, but instead, continued to promote the drug for
18 sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis
19 Drug Advisory Committee meetings.

20 38. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily
21 withdraw" Bextra from the U.S. market, stating:

22 " . . . the Agency has concluded that the overall risk versus benefit
23 profile of Bextra is unfavorable. This conclusion is based on the
24 potential increased risk for serious cardiovascular (CV) adverse
25 events, which appears to be a class effect of non-steroidal anti-
26 inflammatory drugs (NSAIDs) (excluding aspirin), an increased
27 risk of serious skin reactions (e.g. toxic epidermal necrolysis,
28 Stevens-Johnson syndrome, erythema multiforme) compared to
other NSAIDs, and the fact that Bextra has not been shown to offer
any unique advantage over the other available NSAIDs."

39. FDA Alert for Healthcare Professionals, April 7, 2005.

1 Continuing, the FDA noted:

2
3 “Bextra has been demonstrated to be associated with an
4 increased risk of serious adverse CV events in two short-term trials
5 in patients immediately post-operative from coronary artery bypass
6 graft (CABG) surgery FDA has concluded that it is reasonable
7 to extrapolate the adverse CV risk information for Bextra from the
8 short-term CABG trials to chronic use given the fact that other
9 COX-2 selective NSAIDs have been shown in long-term controlled
10 clinical trials to be associated with an increased risk of serious
11 adverse CV events (e.g., death, MI, stroke), and the well described
12 risk of serious, and often life-threatening gastrointestinal
13 bleeding To date, there have been no studies that demonstrate
14 an advantage of Bextra over other NSAIDs that might offset the
15 concern about the[] serious skin risks, such as studies that show a GI
16 safety benefit, better efficacy compared to other products, or
17 efficacy in a setting of patients who are refractory to treatment with
18 other products.”

19 40. The scientific data available during and after Bextra’s approval process
20 made clear to Defendants that their formulation of Bextra would cause a higher risk of blood
21 clots, stroke and/or myocardial infarctions among Bextra consumers, alerting them to the need to
22 do additional and adequate safety studies.

23 41. As stated by Dr. Topol on October 21, 2004, in *The New England Journal*
24 *of Medicine*, outlining Defendants’ failure to have conducted the necessary trials before
25 marketing to humans “ . . . it is mandatory to conduct a trial specifically assessing cardiovascular
26 risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with
27 established coronary artery disease, who frequently have coexisting osteoarthritis requiring
28 medication and have the highest risk of further cardiovascular events.”

29 42. Dr. Topol was also the author on the study published in August 2001 in
30 JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in
31 persons who used COX-2 inhibitors.

32 43. Based upon readily available scientific data, Defendants knew, or should
33 have known, that their pre-approval testing of Bextra did not adequately represent the cross-
34 section of individuals who were intended consumers and therefore, likely to take Bextra.
35 Therefore, Defendants’ testing and studies were grossly inadequate. *See, e.g.*, PDR entry for
36

1 Bextra (noting that: “**Platelets**: In four clinical studies with young and elderly (>/=65 years)
2 subjects, single and multiple doses up to 7 day mg BID had no effect on platelet aggregation”).
3

4 44. Had Defendants done adequate testing prior to approval and “market
5 launch,” (rather than the extremely short duration studies done on the small size patient base that
6 was actually done) Pharmacia and Searle’s scientific data would have revealed significant
7 increases in incidence of strokes and myocardial infarctions among the intended and targeted
8 population of Bextra consumers. Adequate testing would have shown that Bextra possessed
9 serious side effects for individuals such as Plaintiff. Defendants should have taken appropriate
10 measures to ensure that their defectively designed product would not be placed in the stream of
11 commerce and/or should have provided full and proper warnings accurately and fully reflecting
12 the scope and severity of symptoms of those side effects should have been made.

13 45. In fact, post-market approval data did reveal increased risks of clotting,
14 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants
15 in order for them to gain significant profits from continued Bextra sales.

16 46. Defendants’ failure to conduct adequate testing and/or additional testing
17 prior to “market launch” was based upon their desire to generate maximum financial gains for
18 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2
19 inhibitor market.

20 47. At the time Defendants manufactured, advertised, and distributed Bextra to
21 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding
22 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants
23 knew that if such increased risks were disclosed, consumers such as Plaintiff would not purchase
24 Bextra, but instead would purchase other cheaper and safer NSAIDs.

25 **D. Facts Regarding Defendants’ Marketing and Sale of Bextra**

26 48. At all times relevant herein, Defendants engaged in a marketing campaign
27 with the intent that consumers would perceive Bextra as a safer and better drug than its other
28 NSAIDs and, therefore, purchase Bextra.

1 49. Defendants widely and successfully marketed Bextra throughout the
2 United States by, among other things, conducting promotional campaigns that misrepresented the
3 efficacy of Bextra in order to induce a widespread use and consumption. Bextra was represented
4 to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made
5 misrepresentations by means of media advertisements, and statements contained in sales literature
6 provided to Plaintiff's prescribing physicians.

7 50. Despite knowledge of the dangers presented by Bextra, Defendants and
8 Defendants' predecessors in interest, through their officers, directors and managing agents for the
9 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy
10 the known defects of Defendants' product, Bextra, and failed to warn the public, including
11 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,
12 Bextra. Defendants and their officers, agents and managers intentionally proceeded with the
13 inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product,
14 Bextra, knowing that persons would be exposed to serious potential danger, in order to advance
15 their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a
16 conscious disregard for the safety of the public and particularly of Plaintiff.

17 51. In an elaborate and sophisticated manner, Defendants aggressively
18 marketed Bextra directly to consumers and medical professionals (including physicians and
19 leading medical scholars) in order to leverage pressure on third party payers, medical care
20 organizations, and large institutional buyers (*e.g.*, hospitals) to include Bextra on their
21 formularies. Faced with the increased demand for the drug by consumers and health care
22 professionals that resulted from Defendants' successful advertising and marketing blitz, third
23 party payers were compelled to add Bextra to their formularies. Defendants' marketing campaign
24 specifically targeted third party payers, physicians, and consumers, and was designed to convince
25 them of both the therapeutic and economic value of Bextra.

26 52. Defendants represented that Bextra was similar to ibuprofen and naproxen
27 but was superior because it lacked any of the common gastrointestinal adverse side effects
28

1 associated with these and other non-steroidal anti-inflammatory drugs (“NSAIDS”). For instance,
2 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with
3 long-term use. Defendants promoted Bextra as a safe and effective alternative that would not
4 have the same deleterious and painful impact on the gut, but that would be just as effective, if not
5 more so, for pain relief.

6 53. Bextra possessed dangerous and concealed or undisclosed side effects,
7 including the increased risk of serious cardiovascular events, such as heart attacks, unstable
8 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as
9 strokes. In addition, Bextra was no more effective than traditional and less expensive NSAIDs
10 and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal
11 bleeding. Defendants chose not to warn about these risks and dangers.

12 54. Defendants knew of these risks before the U.S. Food and Drug
13 Administration (the “FDA”) approved Bextra for sale on November 16, 2001, but Defendants
14 ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied
15 inefficacy in its promotion, advertising, marketing, and sale of Bextra. Defendants’ omission,
16 suppression, and concealment of this important information enabled Bextra to be sold to, and
17 purchased, or paid for by, the Consumers at a grossly inflated price.

18 55. Consequently, Bextra captured a large market share of anti-inflammatory
19 drugs prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002),
20 sales of Bextra exceeded \$1.5 billion, despite the significantly higher cost of Bextra as compared
21 to other pain relievers in the same family of drugs.

22 56. It was not until April 7, 2005, that Defendants finally acknowledged
23 Bextra’s deleterious side effects and announced that they were withdrawing the drug from the
24 worldwide market based on what it misleadingly termed “new” and “unexpected” evidence
25 linking Bextra to an increased risk of heart attacks and strokes.

26 57. Had Defendants done adequate testing prior to approval and “market
27 launch,” Pharmacia’s scientific data would have revealed significant increases in stroke and
28

1 myocardial infarction amongst the intended population of BEXTRA consumers. Adequate
2 testing would have shown that BEXTRA possessed serious side effects. Defendants should have
3 taken appropriate measures to ensure that their defectively designed product would not be placed
4 in the stream of commerce and/or should have provided full and proper warnings accurately and
5 fully reflecting the scope and severity of symptoms of those side effects should have been made.
6

7 58. In fact, post-market approval data did reveal increased risks of clotting,
8 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants
9 in order for them to gain significant profits from continued BEXTRA sales.

10 59. Defendants' failure to conduct adequate testing and/or additional testing
11 prior to "market launch" was based upon their desire to generate maximum financial gains for
12 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2
13 inhibitor market.

14 60. At the time Defendants manufactured, advertising, and distributed
15 BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld
16 information regarding the increased risks of hypertension, stroke and/or myocardial infarctions
17 because Defendants knew that if such increased risks were disclosed, consumers such as plaintiff
18 would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAID drugs.

19 61. At all times relevant herein, Defendants engaged in a marketing campaign
20 with the intent that consumers, including plaintiff, and their doctors would perceive BEXTRA as
21 a better drug than its competitors and, therefore, purchase BEXTRA.

22 62. Defendants widely and successfully marketed BEXTRA throughout the
23 United States by, among other things, conducting promotional campaigns that misrepresented the
24 efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was
25 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.
26 Defendants made misrepresentations by means of media advertisements, and statements
27 contained in sales literature provided to Plaintiff's prescribing physicians.
28

63. Prior to manufacturing, sale and distribution of BEXTRA, Defendants, through their officers, director and managing agents, had notice and knowledge from several sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As such, BEXTRA consumers, including Plaintiff, were unreasonably subject to risk of injury or death from the consumption of Defendants' product, BEXTRA.

Despite such knowledge, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' product, BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their officers, agents and managers intentionally proceeded with the inadequate testing, and then the manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF:

64. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

65. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty included the duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

1 66. At all relevant times to this action, Defendants owed a duty to properly
2 warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical
3 drug BEXTRA.

4 67. Defendants breached their duties by failing to exercise ordinary care in the
5 preparation, design, research, testing, development, manufacturing, inspection, labeling,
6 marketing, promotion, advertising and selling of BEXTRA, including:

7 a. failing to use due care in the preparation and development of
8 BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were
9 ingested;

10 b. failing to use due care in the design of BEXTRA to prevent the
11 aforementioned risk of injuries to individuals when the drugs were ingested;

12 c. failing to conduct adequate pre-clinical testing and research to
13 determine the safety of BEXTRA;

14 d. failing to conduct adequate post-marketing surveillance and
15 exposure studies to determine the safety of BEXTRA;

16 e. failing to completely, accurately and in a timely fashion, disclose
17 the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff,
18 consumers, the medical community, and the FDA;

19 f. failing to accompany BEXTRA with proper warnings regarding all
20 possible adverse side effects associated with the use of BEXTRA;

21 g. failing to use due care in the manufacture, inspection, and labeling
22 of BEXTRA to prevent the aforementioned risk of injuries to individuals who used BEXTRA;

23 h. failing to use due care in the promotion of BEXTRA to prevent the
24 aforementioned risk of injuries to individuals when the drugs were ingested;

25 i. failing to use due care in the sale and marketing of BEXTRA to
26 prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

j. failing to use due care in the selling of BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

k. failing to provide adequate and accurate training and information to the sales representatives who sold BEXTRA;

1. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of BEXTRA; and

m. being otherwise reckless, careless and/or negligent.

68. Despite the fact that Defendants knew or should have known that

BEXTRA caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market BEXTRA to consumers, including Plaintiff, when safer and more effective methods of pain relief were available.

69. Defendants were, or should have been, had they exercised reasonable care, in possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of BEXTRA.

70. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

71. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff **sustained serious cardiovascular injuries including a major heart attack**. Plaintiff required healthcare and services incurring direct medical losses and costs including care for hospitalization, physician care, monitoring, treatment, medications, and supplies.

72. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

1 73. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
2 compensatory damages, and exemplary and punitive damages together with interest, the costs of
3 suit and attorneys' fees and such other and further relief as this Court deems just and proper.
4

5 **SECOND CLAIM FOR RELIEF:**
6 **Strict Liability**

7 74. Plaintiff incorporates by reference all previous paragraphs of this
Complaint as if fully set forth herein and further alleged as follows:

8 75. At all times relevant to this action, Defendants were suppliers of BEXTRA,
9 placing the drug into the stream of commerce. BEXTRA was expected to and did reach Plaintiff
10 without substantial change in the condition in which it was manufactured and sold.

11 76. BEXTRA was unsafe for normal or reasonably anticipated use.

12 77. BEXTRA was defective in design or formulation because when it left the
13 hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous
14 than an ordinary consumer would expect. BEXTRA was also defective and unreasonably
15 dangerous in that the foreseeable risk of injuries from BEXTRA exceeded the benefits associated
16 with the design and/or formulation of the product.

17 78. Bextra is unreasonably dangerous: a) in construction or composition; b) in
18 design; c) because an adequate warning about the product was not provided; and d) because it
19 does not conform to an express warranty of the manufacturer about the product.

20 79. The characteristics of Bextra that render it unreasonably dangerous existed
21 at the time the product left the control of the manufacturer or resulted from a reasonably
22 anticipated alteration or modification of the product.

23 80. The BEXTRA manufactured and supplied by Defendants was also
24 defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and
25 inadequate reporting regarding the results of the clinical trials, testing and study. Defendants
26 failed to perform adequate testing before exposing Plaintiff to the medication, testing which
27

1 would have shown that BEXTRA had the potential to cause serious side effects including **heart**
2 **attacks** like that which affected Plaintiff.

3 81. The BEXTRA manufactured and supplied by Defendants was defective
4 due to inadequate post-marketing warnings or instructions because, after Defendants knew or
5 should have known of the risk of injuries from BEXTRA, they failed to provide adequate
6 warnings to the medical community and the consumers, to whom they were directly marketing
7 and advertising BEXTRA; and, further, it continued to affirmatively promote BEXTRA as safe
8 and effective.

9 82. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised
10 and promoted defectively by Defendants, and as a direct and proximate cause of Defendants'
11 defective design of BEXTRA, Plaintiff used BEXTRA rather than other safer and cheaper
12 NSAIDs. As a result, Plaintiff suffered the personal injuries described above.

13 83. Information given by Defendants to the medical community and to the
14 consumers concerning the safety and efficacy of BEXTRA, especially the information contained
15 in the advertising and promotional materials, did not accurately reflect the potential side effects of
16 BEXTRA.

17 84. Had adequate warnings and instructions been provided, Plaintiff would not
18 have taken BEXTRA as did, and would not have been at risk of the harmful side effects
19 described herein.

20 85. Defendants acted with conscious and deliberate disregard of the
21 foreseeable harm caused by BEXTRA.

22 86. Plaintiff could not, through the exercise of reasonable care, have
23 discovered BEXTRA's defects or perceived the dangers posed by the drug.

24 87. As a direct and proximate consequence of Defendants' acts, omissions, and
25 misrepresentations described herein, the Plaintiff **sustained serious cardiovascular injuries**.
26 Plaintiff required healthcare and services incurring direct medical losses and costs including care
27 for hospitalization, physician care, monitoring, treatment, medications, and supplies.

88. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

89. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF:
Breach of Express Warranty

90. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

91. Defendants expressly represented to Plaintiff and other consumers and the medical community that BEXTRA was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

92. These warranties came in the form of:

a. Defendants' public written and verbal assurances of the safety and efficacy of BEXTRA;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of BEXTRA, especially to the long-term ingestion of BEXTRA;

c. Verbal and written assurances made by Defendants regarding BEXTRA and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA during the period of Plaintiff's ingestion of BEXTRA, and:

1 e. advertisements.

2 93. The documents referred to above were created by and at the direction of
3 Defendants.

4 94. Defendants knew or had reason to know that BEXTRA did not conform to
5 these express representations in that BEXTRA is neither as safe nor as effective as represented,
6 and that BEXTRA produces serious adverse side effects.

7 95. BEXTRA did not and does not conform to Defendants' express
8 representations because it is not safe, has numerous and serious side effects, including unwarned-
9 of side effects, and causes severe and permanent injuries.

10 96. Plaintiff, other consumers, and the medical community relied upon
11 Defendants' express warranties.

12 97. As a direct and proximate consequence of Defendants' acts, omissions, and
13 misrepresentations described herein, the Plaintiff **sustained serious cardiovascular injuries**.
14 Plaintiff required healthcare and services incurring direct medical losses and costs including care
15 for hospitalization, physician care, monitoring, treatment, medications, and supplies.

16 98. Defendants' conduct was committed with knowing, conscious, wanton,
17 willful, and deliberate disregard for the value of human life and the rights and safety of
18 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
19 as to punish Defendants and deter them from similar conduct in the future.

20 99. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
21 compensatory damages, and punitive and exemplary damages together with interest, the costs of
22 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

24 **FOURTH CLAIM FOR RELIEF:**
Breach of Implied Warranty

25 100. Plaintiff incorporates by reference all of the paragraphs of this Complaint
26 as if fully set forth herein.

1 101. Defendants manufactured, distributed, advertised, promoted, and sold
2 BEXTRA.

3 102. At all relevant times, Defendants knew of the use for which BEXTRA was
4 intended and impliedly warranted the product to be of merchantable quality and safe and fit for
5 such use.

6 103. Defendants were aware that consumers, including Plaintiff, would use
7 BEXTRA for treatment of pain and inflammation and for other purposes.

8 104. Plaintiff and the medical community reasonably relied upon Defendants'
9 judgment and expertise to only sell them or allow them to prescribe BEXTRA only if it was
10 indeed of merchantable quality and safe and fit for its intended use. Consumers, including
11 Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for
12 BEXTRA.

13 105. BEXTRA reached consumers, including Plaintiff, without substantial
14 change in the condition in which it was manufactured and sold by Defendants.

15 106. Defendants breached their implied warranty to consumers, including
16 Plaintiff; BEXTRA was not of merchantable quality or safe and fit for its intended use.

17 107. As a direct and proximate consequence of Defendants' acts, omissions, and
18 misrepresentations described herein, the Plaintiff **sustained serious cardiovascular injuries**.
19 Plaintiff required healthcare and services incurring direct medical losses and costs including care
20 for hospitalization, physician care, monitoring, treatment, medications, and supplies.

21 108. Defendants' conduct was committed with knowing, conscious, wanton,
22 willful, and deliberate disregard for the value of human life and the rights and safety of
23 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
24 as to punish Defendants and deter them from similar conduct in the future.

25 109. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
26 compensatory damages and punitive and exemplary damages together with interest, the costs of
27 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CLAIM FOR RELIEF:
Fraudulent Misrepresentation & Concealment

110. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

111. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of BEXTRA, and their intentional dissemination of promotional and marketing information about BEXTRA for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about BEXTRA's risks and harms to doctors and consumers.

112. Defendants made fraudulent affirmative misrepresentations with respect to BEXTRA in the following particulars:

f. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that BEXTRA had been tested and found to be safe and effective for the treatment of pain and inflammation; and

g. Defendants represented that BEXTRA was safer than other alternative medications.

113. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of BEXTRA.

114. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that BEXTRA had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

115. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of BEXTRA including, but not limited to,

1 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'
2 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the
3 serious nature of the risks associated with the use of BEXTRA in order to increase its sales.

4 116. The representations and concealment were undertaken by Defendants with
5 an intent that doctors and patients, including Plaintiff, rely upon them.

6 117. Defendants' representations and concealments were undertaken with the
7 intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to
8 induce and encourage the sale of BEXTRA.

9 118. Defendants' fraudulent representations evinced their callous, reckless,
10 willful, and depraved indifference to the health, safety, and welfare of consumers, including
11 Plaintiff.

12 119. Plaintiff's physician and Plaintiff relied on and were induced by
13 Defendants' misrepresentations, omissions, and/or active concealment of the dangers of
14 BEXTRA in selecting BEXTRA treatment.

15 120. Plaintiff and the treating medical community did not know that the
16 representations were false and were justified in relying upon Defendants' representations.

17 121. Had Plaintiff been aware of the increased risk of side effects associated
18 with BEXTRA and the relative efficacy of BEXTRA compared with other readily available
19 medications, Plaintiff would not have taken BEXTRA as did.

20 122. As a direct and proximate consequence of Defendants' acts, omissions, and
21 misrepresentations described herein, the Plaintiff **sustained serious cardiovascular injuries**.
22 Plaintiff required healthcare and services incurring direct medical losses and costs including care
23 for hospitalization, physician care, monitoring, treatment, medications, and supplies.

24 123. Defendants' conduct was committed with knowing, conscious, wanton,
25 willful, and deliberate disregard for the value of human life and the rights and safety of
26 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
27 as to punish Defendants and deter them from similar conduct in the future.

1 124. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
2 compensatory damages, and punitive and exemplary damages together with interest, the costs of
3 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.
4

5 **SIXTH CLAIM FOR RELIEF**
6 **(Unjust Enrichment)**

7 125. Plaintiff incorporates by reference all previous paragraphs of this
Complaint as if fully set forth herein.

8 126. At all times relevant to this action, Defendants were the manufacturers,
9 sellers, and/or suppliers of BEXTRA.

10 127. Plaintiff paid for BEXTRA for the purpose of managing pain safely and
11 effectively.

12 128. Defendants have accepted payment from Plaintiff for the purchase of
13 BEXTRA.

14 129. Plaintiff did not receive the safe and effective pharmaceutical product for
15 which paid.

16 130. It is inequitable and unjust for Defendants to retain this money because the
17 Plaintiff did not in fact receive the product Defendant represented BEXTRA to be.

18 131. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
19 equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court
20 deems just and proper.

23 **PRAYER FOR RELIEF**

24 WHEREFORE, Plaintiff requests the following relief:

25 132. General damages in excess of the jurisdictional amount of this Court;

26 133. Consequential damages;

27 134. Disgorgement of profits;

- 1 135. Restitution;
- 2 136. Punitive and exemplary damages;
- 3 137. Pre-judgment and post-judgment interest as provided by law;
- 4 138. Recovery of Plaintiff's costs including, but not limited to, discretionary
- 5 Court costs of these causes, and those costs available under the law, as well as expert fees and
- 6 attorneys' fees and expenses, and costs of this action; and
- 7 139. Such other and further relief as the Court deems just and proper.
- 8
- 9

10 **Dated:** April 4, 2008

11 Respectfully submitted,

12 ARMSTRONG & GUY LAW OFFICES, LLC

13 By: _____

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DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: April 11, 2008

Respectfully submitted,

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